

— *The BioElites* — Engineering our Future

Despite promised benefits, the latest developments in the human biotechnology industry have grave ethical implications for our genetic privacy and integrity.

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THE REVOLUTION IN HUMAN BIOTECHNOLOGY

The 'gods' of the new millennium may not be aliens from another planet, but multi-billion-dollar biotechnology companies that own plant, animal and human genes. The gods will create new life through genetic manipulation, cloning and tissue culturing. Their disease-resistant creations, developed in sterile laboratories, will be the alien life-forms of the 21st century.

What happens if elite groups have control of our genetic destiny? What happens if human clones are produced; if humans are genetically adapted for deep-space travel; if education, employment and insurance are determined by our genes; if human genes become the intellectual property portfolios of transnational corporations?

The new world of human biotechnology currently being ushered in by genomic corporations, technocratic government agencies and the pioneers of medical science makes Aldous Huxley's *Brave New World* look like a freedom-loving paradise. Human biotechnology is currently undergoing a revolution. Many of the techniques Huxley envisaged for the distant future are already available or are being forecast by reputable scientists.

Human genes have become industrial commodities to be bought, sold and patented. Transnational genomic corporations, known as the "Life Sciences" industries, are swallowing up biotechnology companies, and a few enormous genomic corporations are consolidating the ownership of life.

The government-sponsored Human Genome Project, haunted by the shadow of Nazi eugenics and likened in size and importance to the Manhattan and Apollo projects, has given biotechnology a shot in the arm.

Operating in a virtual regulation and policy vacuum, where compliance to 'standards' and 'ethics' is voluntary, the rampant and uncontrolled progress of the human biotech industry has the capacity to impact seriously upon our collective destiny.

Genetic engineering and other disciplines such as embryo transfer, molecular biology and tissue culture are part of modern human biotechnology.

Biotechnology involves the development of 'products' by exploiting biological processes or substances for human purposes. It involves using organisms to provide us with food, medicine, clothes and other products. Traditional biotechnology was based on activities such as the farming of animals and plants and the use of micro-organisms in the manufacture of beer, wine, bread, yoghurt and cheese.

However, since the mid-1970s, when a small group of individuals began to realise that computers and gene sequencing were a natural marriage, advances in biotechnology have given the discipline a more menacing edge. What started as pioneering research to develop 'cures' for genetic diseases, cancer and AIDS has turned into a lucrative, profit-motivated industry.

To its advocates, modern biotechnology is ideologically neutral. Properly supported, biotechnology can bring immense benefits to humanity, for it is infinitely adaptable to counter all sorts of unforeseen threats. If we cast it down through hostility or faint-heartedness, we will be losers.

Critics see biotechnology as the expansion, misapplication and institutionalisation of a particular scientific creed, with the potential for the devaluation and exploitative manipulation of life. Jeremy Rifkin, quoted in *The Human Body Shop: The Engineering and Marketing of Life*, describes human biotechnology as "the devil at the door, cleverly disguised as an engineer and an entrepreneur".

LICENSING LIFE: THE BIOTECH BILLIONS

On 14 March 1995, the United States Patent and Trademark Office issued the first patent on a human cell line to the US National Institutes of Health (NIH). The unmodified cell line was drawn from an indigenous person from Papua New Guinea.

Human life is now officially a commodity whose ownership can be legally enforced by patents awarded to genomic corporations on human genes and their by-products.

Since this new and outrageous era in intellectual property was launched, the 'life industries' have raced to identify and commercialise human genes and other human biological materials.

The Rural Advancement Foundation International (RAFI) describes the frenzied endeavours to profit from human biological materials as a modern-day gold rush, a gene rush:

...silent and reckless with incalculable stakes for humankind...the commodity they seek to exploit is not gold but biological information. The raw material they need is human DNA: the blueprint of human life.

Each human cell contains up to 100,000 genes. A single patented cell line can be worth US\$1.5 billion dollars per year to a company involved in the life sciences industries. Research conducted by RAFI reveals that more than 1,000 DNA patents on sequences have already been issued to over 300 companies and government institutions.

Just one small portion of the human biotechnology industry can yield lucrative profits. The US consulting firm Frost and Sullivan estimates that the worldwide market for cell lines and tissue cultures brought in US\$427.6 million in corporate revenues in 1996. Frost and Sullivan predict that the market will grow at an average annual rate of 13.5 per cent over the next seven years, to be worth US\$914.1 million by 2002.

Biotech companies are rushing to isolate a plethora of disease-carrying genes, including the genes that cause colon cancer, lung cancer, prostate cancer, cystic fibrosis, heart disease and asthma. Once patented, these genes are worth billions of dollars in licensing fees and spinoffs from the manufacture of other pharmaceuticals and gene technology.

Some patents already awarded include:

- The hepatitis C virus sequence, patented by the US biotech company, Chiron Corporation.
- The gene for breast cancer susceptibility, patented by Myriad Genetics.
- A European patent on the use of stored stem cells from umbilical cord blood, granted to the US company Biocyte Corporation. Such cells are widely thought to hold considerable therapeutic promise for bone marrow transplantation and gene therapy.
- The gene for H2-relaxin, a protein produced within the ovaries which relaxes connective tissue to allow a woman's pelvic girdle to widen during pregnancy and while giving birth.

Once a company has a patent (say, on a gene-sequencing right), it must be paid a royalty or licence fee by others using that sequence. Chiron claims that it invests more than five times its income from hepatitis C licensing in its research program—a total of US\$344 million in 1995. Thus, the income received from the hepatitis C virus sequence licensing fees would be valued at US\$68.8 million for that year alone.

Companies involved in human, plant and animal biotechnology

are bound up in a web of alliances and interests. Research and development is concentrated in the hands of a few companies. One example is the "superclub" set up by the France-based multinational drugs company Rhône-Poulenc Rorer, and operated by its subsidiary, RPR Gencell of Collegeville, Pennsylvania, USA.

The "superclub" is touted as an admirable venture because it will accelerate the development of gene therapies for cancer, cardiovascular disease, obesity, etc., through the use of shared data and technology. It will also accelerate the profits raked in by RPR Gencell. One of the conditions of joining the "superclub" is that researchers should withhold publication of their findings for a year until RPR Gencell files for patents to protect discoveries or inventions. This gives RPR Gencell a great deal of control over researchers' findings.

The 14 "superclub" members include:

- CNRS (France's National Centre for Scientific Research)
- Généthon, Paris
- Gustave Roussy Institute, Paris
- Transgène, Paris
- Applied Immune Sciences, Santa Clara, California
- Darwin Molecular, Seattle, Washington
- Genetix Pharmaceuticals, New York
- Introgen Therapeutics, Houston, Texas
- Lawrence Berkeley Human Genome Center, Berkeley, California
- Virogenetics, Troy, New York

Another example is the company Human Genome Sciences

(HGS) of Rockville, Maryland, which owns the details of DNA sequences that could identify 35,000 human genes—more than a third of the total thought to exist.

In October 1994, HGS announced that any researcher who wanted to use the information held by HGS could do so for free, on the basis that if the researcher came up with something that could be commercialised, such as a test or treatment for a disease, HGS would have the right to negotiate a marketing contract. HGS sees this seemingly modest demand as a way to

pay back its investors, such as the pharmaceuticals company SmithKline Beecham which has poured US\$100 million into HGS and its non-profit arm, The Institute for Genomic Research (TIGR).

In biotechnology, as in many other fields, government agencies are forming alliances with corporations. In 1995, the US Patent and Trademark Office issued a patent to the US National Institutes of Health, covering the principle of removing cells from a patient, altering their genetic makeup and returning them to the body. Almost all gene therapy trials that have been approved so far rely on this technique. The NIH has given GTI, of Gaithersburg, Maryland, exclusive rights to develop the technique commercially. Rival companies wanting to do research must now pay a licensing fee to GTI.

Alleged industrial espionage is rife as biotech companies proceed with litigation against each other. One legal battle involves mice that have been 'developed' to secrete human antibodies which may help treat AIDS and cancer. The 'humanised' mice, worth millions, were the subject of a bitter dispute between the two US companies Cell Genesys and GenPharm. Cell Genesys withdrew its legal action upon learning that the US Patent and

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Trade Mark Office had awarded GenPharm a third patent on the mouse 'technology'. Cell Genesys will now use its own patents to battle GenPharm.

AGRICULTURAL BIOTECHNOLOGY: THE SAME STORY

Not only is ownership of human biological materials being consolidated by "life sciences" companies; but the products of agriculture have met with the same fate.

The "life sciences" company Monsanto, with 28,000 employees, has a net worth of US\$9 billion and pours US\$200 million per year into research. Monsanto's Robert Fraley said of their agricultural biotechnology interests:

...what you're seeing is not just a consolidation of seed companies, it's really a consolidation of the entire food chain.

Through its shareholdings, acquisitions and licensing agreements, Monsanto has a controlling interest in the worldwide production of canola oil, soya, cotton and maize, to name a few.

Last year, the two giant pharmaceutical/chemical companies Ciba-Geigy and Sandoz amalgamated in what was the largest corporate merger in history—even larger than the Time-Life merger. The resultant new company, Novartis (whose Latin name means "new skills" or "new arts"), spans the health care, nutrition and agribusiness industries. Its estimated global net worth is 58 billion Swiss francs—more than the value of most nations. Novartis' global research expenditure for 1996 was US\$3.1 billion, while worldwide sales revenue for 1996 was US\$27 billion.

BIOPIRACY OF HUMAN GENETIC MATERIAL

Third world populations and indigenous peoples are currently being exploited by governments and genomic corporations seeking to commercialise genes and other biological materials.

When the US government patented the cell line of a Papua New Guinean indigenous person, there was no documentation of his informed consent or any approval from the Papua New Guinea government.

Documentation obtained by RAFI under Freedom of Information legislation revealed that the patented cells from the Hagahai indigenous person from Papua New Guinea had potential in the diagnosis and treatment of leukaemia and related retroviral diseases. These genes are now the exclusive property of the US government. Various acts of biopiracy have been the subject of investigation by RAFI, which concludes:

Pieces of indigenous and remote rural peoples' very bodies are now, without any doubt, the potential 'intellectual property' of corporations and governments...

Cells, DNA and other human biological materials are being shuttled into the intellectual property portfolios and cash boxes of the life industries.

RAFI has also raised concerns about the collection, handling and exchange of human tissue samples taking place *ad hoc* across international borders. Perhaps what is most controversial about the patenting of genes and the use of human biological products for profit is that it is all largely taking place in an unregulated market. According to RAFI:

An unfortunate reality currently confronts the enormous number of people who, for clinical and research purposes, give blood or other samples of tissue. They may unwittingly

become a statistic in the international human tissue trade—in some cases even if the tissue donor simply gave blood for a blood bank. Donors' cells may be frozen and/or immortalized and shipped across town, across the world, or both. Genetic profile information from analysis of cells...may be created and placed in a database available to thousands.

RAFI's enquiries revealed one Internet directory of tissue culture-related enterprises that lists 38 companies in the US which specialise in selling cells, cell products and tools for cell culturing. Some have Internet home pages where customers can peruse on-line catalogues of "normal" and/or "mutant" human tissue for sale. Human biological samples are being exchanged and used in ways that donors would not be aware of, nor would be likely to endorse.

THE HUMAN GENOME PROJECT

The aim of the Human Genome Project is to determine the exact genetic structure of our species—the sequence of all of our DNA. The idea for the project has been in the pipeline since the US military began studying the genetic effects of radiation on survivors of Hiroshima and Nagasaki.

In the mid-1970s, technological developments enabled researchers to use high-speed computers to sequence or map genes. Previous methods of gene-mapping relied on laborious hand-made drawings of gene maps.

In the late 1980s, biologists realised that with new technologies they could sequence the entire human genome. For obvious reasons, this 'realisation' was supported by the US government, military, educational institutions and biotech companies. The US government moved quickly to merge funding for various biotech projects.

The Human Genome Project was officially launched in 1991, funded primarily by the Department of Energy and the National Institutes of Health in the USA as well as the

European Commission.

Using high-speed computers and working with zenith nanotechnology (i.e., single molecules), the human genome is now being entered onto the GenBank database at Los Alamos (weapons) Laboratories in New Mexico, USA—site of the Manhattan Project and more recently linked to the alleged Roswell 'alien autopsy' scenario.

Researchers from the far corners of the globe are able to contribute information to GenBank via the Internet. Laboratories are offered 'incentives' to submit genomic information. Another motivation to submit information to GenBank is the growing number of journals that will not publish genomic articles without proof that the authors have submitted their data electronically to GenBank at Los Alamos.

GenBank is operated by the US Department of Energy-owned national laboratory but funded by the National Institutes of Health, the Department of Defense, the National Science Foundation and the Department of Energy. There is also a Human Genome Center at Lawrence Berkeley and at Lawrence Livermore national laboratories.

Once the first complete human DNA sequence is obtained, we will have what has been described as the 'biological grail'—a complete record of the human genome. This will be of great use to the life sciences industries because it will provide a database of

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information from which companies can obtain the DNA sequence, and hence protein sequence, of all the proteins in humans, including those which are the potential targets of new drugs. The Human Genome Project will also be of substantial assistance in medical genetics, including the diagnosis of inherited predisposition to disease.

The first complete human genome sequence is expected to be a 'composite person' with both an X and Y sex chromosome. This would formally make the 'composite person' a male, but 'he' would comprise autosomes taken from men and women of several nations: the United States, European countries and Japan. He would be a multinational, multiracial *mélange*, a kind of "Adam II", his essence encoded for the 21st century and beyond.

THE HUMAN GENOME AS A WEAPON OF WAR

The Human Genome Project is a vital part of the US post-Cold War military strategy. Psychological, biological and defensive technology for conflict short of war is of growing importance. To this end, the human genome was recently declared a potential weapon of war.

Eighty member-countries of the Biological and Toxic Weapons Convention added "molecular biology" and "any application resulting from genomic studies" to the list of technologies, such as genetic engineering, that could possibly be employed as weapons.

Scientists are concerned that aggressors might develop a disease or poison to which only an enemy is genetically susceptible.

The member countries failed to agree to a deadline for monitoring breaches of the convention because of opposition from a group of nations including Russia and India.

In October 1989, at the Human Genome I Conference held in San Diego, USA, James B. Watson, the Human Genome Project's first director (and co-discoverer of DNA's structure in 1953) told the audience:

We have to be aware of the really terrible past of eugenics, where incomplete knowledge was used in a very cavalier and rather awful way, both here in the United States and in Germany. We have to reassure people that their own DNA is private and that no one else can get it...

In light of the above reports about gene patenting, it would seem that Watson's words of caution fell on deaf ears.

HUMAN GENOME DIVERSITY PROJECT

The Human Genome Project should not be confused with the Human Genome Diversity Project (HGDP), which is a separate but related project concerned with collecting cells from over 700 indigenous clans and tribes worldwide.

The unscrupulous methods for collecting cells and the trafficking and trade in indigenous people's biological materials is well documented by the Rural Advancement Foundation International.

The US Navy has also been undertaking its own private research activities involving the collection of cells and tissues from remote tribes and clans in Indonesia, Papua New Guinea, Peru and Colombia. Of particular interest are blood samples containing the retrovirus HTLV-1.

The previously mentioned Hagahai cell line, patented by the US National Institutes of Health, contains the human leukaemia retrovirus HTLV-1. Thymus lymphocytes (T-cells) can be separated

from HTLV-1 blood samples.

As documented by RAFI, several key US research institutes—including the National Cancer Institute and the Centers for Disease Control—and the US Navy have global research programs tasked with collecting blood samples for HTLV-1 research.

Some readers of *NEXUS* will be familiar with the AIDS-HTLV link, reported in 1988 (see the *NEXUS* supplement, *AIDS: The Real Story*). HTLV-1 can be used to manufacture large quantities of the AIDS-related virus, HTLV-3.

NAZI EUGENICS AND ECONOMIC RATIONALISM

A plethora of ethicists and historians have raised concerns about connections between experimental processes involving human biotechnology and the Nazi 'legacy'.

Nazi genetic experiments were not an historical aberration that can be dismissed. The forces that inspired them did not die with them. The Nazis drew inspiration from many sources, not least of which was the eugenics movement in the USA.

Indeed, fear of a eugenics revival is a key anxiety surrounding the Human Genome Project in the United States and Europe.

Eugenics involves any attempt to improve the biological character of a 'race'. Under Adolf Hitler, German scientists—among the most respected in the world before the Nazi era—took part in an ignominious attempt to create an Aryan blue-eyed, blond-

haired master race through genetic manipulation and experimentation.

In a paper titled "Nazi Biomedical Policies", published in the book, *When Medicine Went Mad*, Robert N. Proctor gives this stern reminder:

The Nazis sought to transform problems of racial, sexual or social deviance into medical problems; Germany's social and political problems would be solved by diagnosis, disinfection and surgery. Murder was practised in the name of quarantine; apartheid in the name of public

"...once the human genome has been mapped, it has the potential to become a standard, or norm, for all people—against which we will then be measured for our normality or abnormality."

health...

Could modern 'eugenics' programs be prompted by the engine of economic rationalism now driving the economies of most nations? Policies are characterised as eugenic if their intent is to further a social or public purpose, such as reducing costs or sparing future generations unnecessary suffering.

Could genetic inheritance become a new basis for discrimination? This was a topic of discussion at the Human Genome Organization's Second International Genome Summit, held in Canberra, Australia, in October 1996. It was an informal meeting of about 50 people. Australian GeneEthics Network Coordinator Bob Phelps was the lonely voice of the people in a wilderness of heavyweight experts including scientists and lawyers.

The GeneEthics Network is involved in lobbying against genetic engineering of plants, animals and humans and raising public awareness of biotechnology. Most recently the network has been involved with a campaign against Monsanto's "Roundup Ready" genetically engineered soybean.

At the Australian Genome Summit, one participant, Dr David Cox of the Stanford School of Medicine, California, USA, stated:

Genetic discrimination to exclude people from employment, insurance and access to health care is a potential adverse consequence of the data generated by the Project. Protection against such discrimination should prevail over conflicting

societal values; such protection must be mandated...

Despite moves in the US and Europe to tighten controls on genetic discrimination, to date no such protection exists in Australia.

Bob Phelps of the GeneEthics Network told this writer that: *...once the human genome has been mapped, it has the potential to become a standard, or norm, for all people—against which we will then be measured for our normality or abnormality. It is going to lead potentially to some great discriminations and other adverse social consequences...*

This has great significance for us all. The coercive forces of economic rationalism that equate progress with cost efficiency could dictate that it would be cost-effective to reduce the number of genetically disabled people. People with disabilities or illnesses could become doomed by their genes. Public policy could pressure or even compel people not to bring genetically damaged children into the world for the sake of the gene pool and in the interests of keeping down public health costs.

New genetics techniques that might extend our lives could justify experiments on the terminally ill on the basis that they are 'doomed anyway' and so have 'nothing to lose'. Equally, projects that generate large incomes for researchers and potentially huge profits for private corporations could be oversold.

George Annas, lawyer and Professor of Public Health at Boston University, says there are powerful forces at work in our society that could combine to affect dramatically the rights and welfare of the less than genetically perfect, creating a culture in which people are valued and devalued based on their genetic endowment. Embryos could be screened and nurtured based on genetic quality.

Writing about the Human Genome Project, Annas says that our fetish for efficiency, our quest for immortality, our belief in commercialism and its handmaiden hype will continue the slide down the slippery slope. The question now is: how far and how fast?

THE BIO-ELITES' VISION FOR THE FUTURE

The brave new future that Aldous Huxley depicted is already upon us, with many techniques he envisaged already available or at least being taken seriously by reputable scientists.

The 1995 "foresighting program" conducted by the Australian Science and Technology Council (ASTEC) provides an insight into the future. Under the heading, "Scenario for 2010: Impact of Research into the Human Genome and Environmental Impact on Health", ASTEC suggests that our future may be determined by a genetic profile—which would determine that individuals should eat certain designer foods and have certain designer therapies throughout life to prevent the onset of genetic disease.

If people were not willing to be engineered in such a way, they could be refused insurance, employment and education. This way, genetic destiny would be manipulated by designer foods and designer therapies.

The advocates of the recently developed concept of "auto-evolution" theorise that elite groups of humans should use existing gene technologies to start directing the evolution of their offspring. Auto-evolutionists envisage that in six generations, or 350 years, humans would be unrecognisable.

Other more exotic schemes include 'adapting' humans for deep-space travel. This may sound like a giddy science fiction scenario, but, already, one Australian company is developing pine and eucalypt species that do not require open pollination. It was shown in studies carried out in the "Biosphere" project that the pollinators had difficulty surviving. Is the biotech industry readying to create artificial environments outside the Earth's biosphere in deep space?

Could we 'adapt' the human species to explore the deep oceans, or 'produce' soldiers resistant to agents of biological war? Such proposals are currently under consideration.

In publicity over the recent cloning of "Dolly" the sheep, it seems to have been forgotten that human embryos have already been cloned. In 1993, researchers Stillman and Hall, of George Washington University, USA, cloned 48 human embryos, none of which grew for more than six days.

Dolly, the cloned sheep, born at the Roslin Institute in Scotland in July 1996, was 'unveiled' in February 1997 after patent applications were filed and research papers prepared for publication. The non-profit Roslin Institute is part-funded by PPL Therapeutics, a biotech company formed in 1987 to commercialise the Roslin Institute's research.

According to RAFI, PPL Therapeutics has several human protein products in development and holds a US patent on a method

to produce therapeutic proteins in the milk of transgenic sheep. PPL has research agreements with at least four major pharmaceutical corporations including Novo-Nordisk, American Home Products, Bayer and Boehringer Ingelheim.

Scientists believe that cloned animals with genetically engineered traits will become highly efficient, living drug-factories for 'use' in the manufacture of therapeutic proteins. The market for therapeutic proteins is currently about US\$7.6 billion per annum and is expected to grow to

US\$18.5 billion by 2000.

Cloned animals could be exploited as 'spare parts' factories for humans. Transgenic pig clones, for example, could be genetically engineered to be a source of replacement organs for humans.

In the twilight years of the 20th century, human biotechnology joins the ranks of environmental decay, nuclear conflict, surveillance technology, monopoly ownership and government-sponsored corporatism as one of the most dangerous threats to our physical, intellectual and spiritual freedom.

The slide down the slippery slope has already begun, but public opinion *can* dictate how fast and how far we go. If we do not act now, our future will be determined by the bio-elites. ∞

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